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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/679,378 | 10/07/2003 | David Carlson | 39147-0016 | 4289 |

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| EXAMINER |
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CHUNDURU, SURYAPRABHA

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| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/679,378 | CARLSON ET AL. | |
| | Examiner | Art Unit | |
| | Suryaprabha Chunduru | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed October 26, 2005 has been entered.

Status of the Application

2. Claims 1-12, 14-15 are pending. Claim 1 is amended. Claims 13, and 16-20 are cancelled.

All amendments and arguments have been thoroughly reviewed and deemed persuasive in view of amendment. The rejections made in the previous office action are withdrawn in view of the amendment. The action is made Final necessitated by amendment.

New Grounds of rejections necessitated by amendment

Claim interpretation

3. The term "about" is not defined in the instant specification and is broader in scope. Thus it can include (+/- 10) of any number around the given range concentration of stabilizing agent, chelating agent and a buffering agent. Further the term "highly basic solution" is broader in scope and the instant specification defines a highly basic solution as having a pH at least about 13.0. Thus the relative term 'about' includes any number around said given pH.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 7-8, 10-11, 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Lai et al. (USPN.6,503,716).

Lai et al. teach a method of claim 1, 14, for extracting DNA from a biological sample, wherein the biological sample is human hair containing no hair root (see col. 26, line 19-31, col. 11, line 32-41), said method comprising contacting the sample with a basic solution (pH about 7 to about 10.5, see col. 3, line 26-) comprising an effective concentration of a chelating agent, an effective concentration of a stabilizing agent, and an effective concentration of a buffering agent (see col. 26, line 19-31, col. 3, line 1-55).

With regard to claims 1, 3, 7, 10, Lai et al. teach that said stabilizing agent is an alkali metal silicate salt (sodium metasilicate) in a concentration of about 1-500M (see col. 3, line 1-9, col. 6, line 40-46).

With regard to claims 4, 8, 11, Lai et al. teach that said buffering agent comprises an alkali metal phosphate salt in a concentration about 1-500M (see col. 3, line 31-33, col. 7, line 9-24).

With regard to claims 14-15, Lai et al. teach that said hair is human hair and said hair is not ground prior to extraction (see col. 26, line 19-31). Accordingly Lai et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1637

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 5-6, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (USPN. 6,503,716) in view of Swason et al. (USPN. 4, 548,608).

Lai et al. teach a method of claim 2 for extracting DNA from a biological sample, wherein the biological sample is human hair containing no hair root (see col. 26, line 19-31, col. 11, line 32-41), said method comprising contacting the sample with a basic solution (pH about 7 to about 10.5, see col. 3, line 26-) comprising an effective concentration of a chelating agent, an effective concentration of a stabilizing agent, and an effective concentration of a buffering agent (see col. 26, line 19-31, col. 3, line 1-55).

With regard to claims 5, 12, Lai et al. teach that said stabilizing agent is an alkali metal silicate salt (sodium metasilicate) in a concentration of about 1-500M (see col. 3, line 1-9, col. 6, line 40-46).

With regard to claims 5, 12, Lai et al. teach that said buffering agent comprises an alkali metal phosphate salt in a concentration about 1-500M (see col. 3, line 31-33, col. 7, line 9-24).

However, Lai et al. did not specifically teach highly basic solution comprising alkali metal gluconate salt (sodium gluconate).

Swanson et al. teach a composition for hair loosening process, said composition comprises sodium gluconate as chelating agents wherein said composition comprises

Art Unit: 1637

predetermined concentrations of sodium gluconate, sodium silicate and sodium phosphate (see col. 2, line 38-52); Swanson et al. also teach that the sodium phosphate due to its buffering ability maintains the high pH (pH-13) thus extending an alkaline contact time with disulfide bonds of protein in the biological sample and sodium gluconate acts as a chelating agent (see col. 3, line 14-39); said composition comprising sodium gluconate facilitates o achieve loosening of hair (see col. 3, line 14-64). Swason et al. also teach that the composition comprises a high level of alkalinity and hydrogen ion concentration with a pH values between 12 to 13.5 (see col. 5, line 11-21).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for extracting DNA as taught by Lai et al. with a step of including highly basic alkaline solution comprising alkali metal gluconate salt, sodium gluconate as chelating agent, as taught by Swanson et al. for the purpose of increasing alkalinity or pH of the solution to promote alkaline lysis because Swanson et al. explicitly taught that sodium gluconate acts as a chelating agent or sequestering agent and facilitates hair loosening process and sodium phosphate due to its buffering ability stabilizes the high pH (pH-13) extends an alkaline contact time with disulfide bonds in hair protein (see col. 3, line 14-39, line 29-58) and said composition is formulated to achieve loosening of the hair protein by attacking active disulfide bonds in cystine hair protein in alkaline solution (see col. 3, line 14-68). An ordinary artisan would have a reasonable expectation of success that modifying the method of DNA extraction as taught by Lai et al. with the inclusion of sodium gluconate as taught by Swanson et al. would result in a highly basic (alkaline) solution that would aid in alkaline lysis of DNA in a hair sample.

Art Unit: 1637

Response to arguments:

6. With regard to the arguments on the claim interpretation regarding stabilizing agent, buffering agent, and highly basic solution, Applicants' arguments are fully considered however, the terms "stabilizing agent, buffering agent" and "highly basic solution" are broader in scope and can include any agents that serve the same function and are not limited to the definitions provided in the specification. With regard to the arguments on the term highly basic solution, Applicants' arguments are fully considered however as stated in MPEP 2145, Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus the highly basic solution representing pH at least 12 or at least about 13 is not present in the instant claims and hence the limitation "highly basic solution" is interpreted as a solution having a pH value greater than an alkaline pH, that is greater than pH 7.0 or any number around the disclosed pH of at least about 13.

7. With regard to the rejection under 35 USC 102(a) as anticipated by Elliot et al., Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment reciting biological sample is a hair containing no hair root.

8. With regard to the rejection under 35 USC 102(b) as being anticipated by Boom et al. Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment reciting biological sample is a hair containing no hair root.

9. With regard to the rejection under 35 USC 102(b) as being anticipated by Fomovskaia Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment reciting biological sample is a hair containing no hair root.

Art Unit: 1637

10. With regard to the rejection under 35 USC 103(a) as being unpatentable over Elliot in view of Swason and Rieck, Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the amendment reciting biological sample is a hair containing no hair root.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

Art Unit: 1637

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

12/3/05